



LAB #: B000000-0000-0
 PATIENT: Sample Patient
 ID: P000000000
 SEX: Male
 DOB: _____

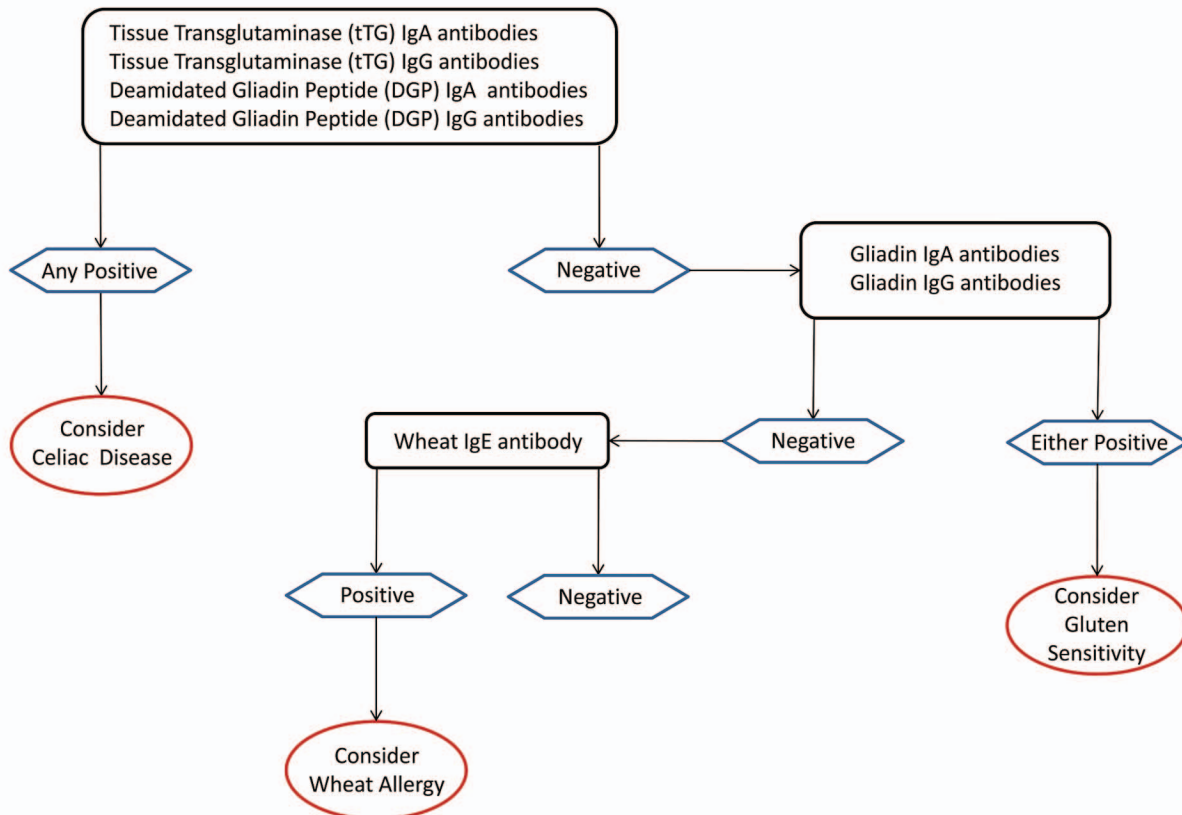
AGE: 20

CLIENT #: 12345
 DOCTOR:
 Doctor's Data, Inc.
 3755 Illinois Ave.
 St. Charles, IL 60174 U.S.A.

Celiac & Gluten Sensitivity; serum

ANTIBODIES							
	RESULT/UNIT	REFERENCE INTERVAL	NEG	WEAK POS	POSITIVE		
Tissue Transglutaminase (tTG) IgA	3.3 U	< 20.0	[Bar chart showing result in NEG column]				
Tissue Transglutaminase (tTG) IgG	< 3.8 U	< 20.0	[Bar chart showing result in NEG column]				
Deamidated Gliadin Peptide (DGP) IgA	43.5 U	< 20.0	[Bar chart showing result in POSITIVE column]				
Deamidated Gliadin Peptide (DGP) IgG	< 2.8 U	< 20.0	[Bar chart showing result in NEG column]				
Gliadin IgA	11.0 U	< 20.0	[Bar chart showing result in POSITIVE column]				
Gliadin IgG	28.0 U	< 20.0	[Bar chart showing result in POSITIVE column]				
Wheat IgE	0.02 kU/L	< 0.08	[Bar chart showing result in NEG column]				
			PERCENTILE				
			2.5 th	16 th	50 th	84 th	97.5 th
Immunoglobulin A (IgA)	1.75 g/L	0.66 - 4.33	[Bar chart showing result between 16 th and 50 th percentiles]				

Celiac Disease/Gluten Sensitivity/Wheat Allergy Cascade



SPECIMEN DATA

Comments:

Date Collected: 08/14/2014
 Date Received: 08/15/2014 <dl: less than detection limit
 Date Completed: 08/19/2014
 Method: Chemiluminescent, Immunoassay

Introduction

Celiac disease (CD) is one of the most common causes of chronic malabsorption and may contribute to a wide variety of chronic conditions including autoimmune disorders and nutritional deficiencies. Celiac disease remains underdiagnosed, as the condition is often asymptomatic for years.

Antibody tests that help diagnose CD and Non-Celiac Gluten sensitivity (NCGS) measure the patient's immune response to gluten exposure; the tests will only be diagnostically accurate if the patient is on a gluten-inclusive diet.

Evaluation of antibodies (tissue transglutaminase and deamidated gliadin peptide) in CD is based on detection of IgA class immunoglobulins. However the incidence of selective IgA deficiency is higher in CD, therefore this test also evaluates the corresponding IgG antibodies.

Patients diagnosed with CD must remain on a gluten-free diet for life and avoid wheat, rye, barley, and other foods that contain gluten and gluten related proteins. A complete list of foods containing wheat may be found at www.doctorsdata.com under "Hidden Sources of Ingredients".

Additional testing recommended to evaluate the effects of CD on the gastrointestinal tract includes:

- Fecal fat
- Lysozyme
- Lactoferrin
- sIgA

The Doctor's Data Comprehensive Stool Analysis would include all of these tests plus additional biomarkers of digestive health and gastrointestinal function.

References:

American Association for Clinical Chemistry (2011) Celiac Disease Tests <http://labtestsonline.org/> accessed 15 May 2014.

Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. The American journal of Gastroenterology vol. 108 (5) p. 656-76; quiz 677.

Sapone, Anna; Lammers, Karen; Casolaro, Vincenzo; Cammarota, Marcella; Giuliano, Maria et al. (2011) Divergence of gut permeability and mucosal immune gene expression in two gluten-associated conditions: celiac disease and gluten sensitivity. BMC Medicine vol. 9 (1) p. 23.

Mothes, Thomas. (2007) Deamidated gliadin peptides as targets for Celiac disease-specific antibodies. Advances in Clinical Chemistry vol.44 p. 44.

Deamidated Gliadin Peptide (DGP) Antibody Negative

The anti-deamidated gliadin peptide (DGP) IgA or IgG results are within normal limits. Celiac disease is associated with a variety of autoantibodies, including tissue transglutaminases (tTG), and deamidated gliadin antibodies; these are considered the most sensitive and specific serologic tests for CD. Antibody responses to deamidated gliadin peptide show high specificity and parallel tTG responses in CD.

A negative DGP IgA antibody result does not exclude an indication of CD in patients who have selective IgA

deficiency, or have been following a gluten-free diet because antibody levels decrease over time. Responses to a gluten-free diet (GFD) vary however, research indicates that weakly positive individuals may become serology-negative within weeks of strict adherence to GFD. Within 6-12 months of adhering to a GFD, 80% of patients will test negative by serology. After five years, more than 90% of patients adhering to the GFD will have negative serologies.

This test result alone is not diagnostic for absence of Celiac disease. The results should be considered in conjunction with the patient's symptoms, immune status, diet, genetic predisposition and medical history.

References:

American Association for Clinical Chemistry (2011) Celiac Disease Tests <http://labtestsonline.org/> accessed 15 May 2014.

Ankelo, M; Kleimola, V; Simell, S; Simell, O; Knip, M et al. (2007) Comparative Usefulness of Deamidated Gliadin Antibodies in the Diagnosis of Celiac Disease Antibody responses to deamidated gliadin peptide show high specificity and parallel antibodies to tissue transglutaminase in developing celiac disease. *Clinical and experimental immunology* vol. 150 (2) p. 285-93.

Parizade, Miriam; Bujanover, Yoram; Weiss, Batya; Nachmias, Vered; Shainberg, Bracha (2009) Performance of serology assays for diagnosing celiac disease in a clinical setting. *Clinical and vaccine immunology : CVI* vol. 16 (11) p. 1576-82.

Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. *The American journal of gastroenterology* vol. 108 (5) p. 656-76; quiz 677.

Vermeersch, Pieter; Geboes, Karel; Mariën, Godelieve; Hoffman, Ilse; Hiele, Martin et al. (2010) Diagnostic performance of IgG anti-deamidated gliadin peptide antibody assays is comparable to IgA anti-tTG in celiac disease. *Clinica chimica acta; international journal of clinical chemistry* vol. 411 (13-14) p. 931-5.

Wang, Ning; Truedsson, Lennart; Elvin, Kerstin; Andersson, Bengt A; Rönnelid, Johan et al. (2014) Serological assessment for celiac disease in IgA deficient adults. *PloS one* vol. 9 (4) p. e93180.

Deamidated Gliadin Peptide (DGP) Antibody High

The serum level of anti-deamidated gliadin peptide (DGP) IgA, IgG or both is higher than expected. An elevated level of DGP IgA or IgG is indicative of Celiac disease.

Celiac disease (CD) is associated with a variety of autoantibodies, including tissue transglutaminases (tTG), and DGP; these are considered the most sensitive and specific blood tests for CD. Antibody responses to DGP show high specificity and parallel tTG responses in CD. The higher the level of anti-DGP IgA or IgG is, the greater the likelihood of a true positive result. For patients with selective total IgA deficiency and in those under age 2, DGP IgA will not likely be elevated and conclusions should be based upon the DGP IgG results.

These test results alone are not diagnostic for Celiac disease. The results should be considered in

conjunction with the patient's symptoms, immune status, diet, genetic predisposition and medical history.

References:

American Association for Clinical Chemistry (2011) Celiac Disease Tests <http://labtestsonline.org/> accessed 15 May 2014.

Ankelo, M; Kleimola, V; Simell, S; Simell, O; Knip, M et al. (2007) Comparative Usefulness of Deamidated Gliadin Antibodies in the Diagnosis of Celiac Disease Antibody responses to deamidated gliadin peptide show high specificity and parallel antibodies to tissue transglutaminase in developing celiac disease. *Clinical and experimental immunology* vol. 150 (2) p. 285-93.

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Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. *The American journal of gastroenterology* vol. 108 (5) p. 656-76; quiz 677.

Vermeersch, Pieter; Geboes, Karel; Mariën, Godelieve; Hoffman, Ilse; Hiele, Martin et al. (2010) Diagnostic performance of IgG anti-deamidated gliadin peptide antibody assays is comparable to IgA anti-tTG in celiac disease. *Clinica chimica acta; international journal of clinical chemistry* vol. 411 (13-14) p. 931-5.

Wang, Ning; Truedsson, Lennart; Elvin, Kerstin; Andersson, Bengt A; Rönnelid, Johan et al. (2014) Serological assessment for celiac disease in IgA deficient adults. *PloS one* vol. 9 (4) p. e93180.

Gliadin Antibody High

The serum level of anti-gliadin antibodies (AGA) IgA, IgG or both is higher than expected. An elevation in either IgA or IgG may indicate gluten sensitivity.

Gluten sensitivity is defined as a gluten reaction that is independent of the IgE reactions of wheat allergy and autoantibody reactions of Celiac disease. In at least 50% of cases, elevated IgA and IgG AGA may be the only serological biomarker in cases of dermatitis herpetiformis or gluten ataxia. Studies have shown that patients with autism, Multiple Sclerosis or schizophrenia are more likely to have elevated IgA AGA levels and that those more likely to have adverse responses to dietary gluten.

Whole purified gliadin that contains the alpha, omega, beta and gamma isoforms is used in the assay.

A negative AGA IgA result does not exclude a possibility of gluten-sensitivity in patients who have selective IgA deficiency, or have been following a gluten-free diet because antibody levels decrease over time.

References:

American Association for Clinical Chemistry (2011) Celiac Disease Tests <http://labtestsonline.org/> accessed 15 May 2014.

Nelsen, David A. Jr., M.D., M.S., (2002) Gluten-Sensitive Enteropathy (Celiac Disease): More Common Than You Think. *Am Fam Physician*. 2002 Dec 15;66(12):2259-2266.

Pietzak, Michelle (2012) Celiac Disease, Wheat Allergy, and Gluten Sensitivity: When Gluten Free Is Not a Fad. *JPEN J Parenter Enteral Nutr* vol. 36 (1_suppl): p. 68S-75S.

Sapone, Anna; Lammers, Karen; Casolaro, Vincenzo; Cammarota, Marcella; Giuliano, Maria et al. (2011) Divergence of gut permeability and mucosal immune gene expression in two gluten-associated conditions: celiac disease and gluten sensitivity. *BMC Medicine* vol. 9 (1) p. 23.

Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. *The American journal of gastroenterology* vol. 108 (5) p. 656-76; quiz 677.

Tissue Transglutaminase (tTG) Antibody Negative

The anti-tissue transglutaminase IgA, IgG or both are within normal limits. An elevated anti-tTG IgA or IgG is indicative of Celiac disease.

A negative tTG IgA antibody result does not exclude a possibility of celiac disease in patients who have very low total IgA or selective total IgA deficiency, or have been strictly following a gluten-free diet as antibody levels decrease over time. Responses to a gluten-free diet (GFD) for patients with normal total IgA vary however; research indicates that weakly positive individuals may become serology-negative within weeks of strict adherence to a GFD. Within 6-12 months of adhering to a GFD, 80% of patients will test negative by serology. After five years, more than 90% of patients adhering to the GFD will have negative serologies. For Celiac total IgA deficient adults, IgG antibodies may decrease more slowly, despite adherence to a gluten-free diet.

This test result alone is not diagnostic for absence of Celiac disease. The results should be considered in conjunction with the patient's symptoms, immune status, diet, genetic predisposition and medical history.

References:

American Association for Clinical Chemistry (2011) Celiac Disease Tests <http://labtestsonline.org/> accessed 15 May 2014.

Parizade, Miriam; Bujanover, Yoram; Weiss, Batya; Nachmias, Vered; Shainberg, Bracha (2009) Performance of serology assays for diagnosing celiac disease in a clinical setting. *Clinical and vaccine immunology : CVI* vol. 16 (11) p. 1576-82.

Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. *The American journal of gastroenterology* vol. 108 (5) p. 656-76; quiz 677.

Dahlbom, Ingrid; Olsson, Martin; Forooz, Nahal Kazemi; Sjöholm, Anders G; Truedsson, Lennart et al. (2005) Immunoglobulin G (IgG) anti-tissue transglutaminase antibodies used as markers for IgA-deficient celiac disease patients. *Clinical and diagnostic laboratory immunology* vol. 12 (2) p. 254-8

Wang, Ning; Truedsson, Lennart; Elvin, Kerstin; Andersson, Bengt A; Rönnelid, Johan et al. (2014) Serological assessment for celiac disease in IgA deficient adults. PloS one vol. 9 (4) p. e93180.

Parizade, Miriam; Bujanover, Yoram; Weiss, Batya; Nachmias, Vered; Shainberg, Bracha (2009) Performance of serology assays for diagnosing celiac disease in a clinical setting. Clinical and vaccine immunology : CVI vol. 16 (11) p. 1576-82.

Rubio-Tapia, Alberto; Hill, Ivor D; Kelly, Ciarán P; Calderwood, Audrey H; Murray, Joseph A (2013) ACG clinical guidelines: diagnosis and management of celiac disease. The American journal of gastroenterology vol. 108 (5) p. 656-76; quiz 677.

Wang, Ning; Truedsson, Lennart; Elvin, Kerstin; Andersson, Bengt A; Rönnelid, Johan et al. (2014) Serological assessment for celiac disease in IgA deficient adults. PloS one vol. 9 (4) p. e93180.

Wheat IgE Negative

The anti-wheat immunoglobulin subclass E (IgE) result is within normal limits.

Immunoglobulin subclass E (IgE) antibodies are used to diagnose type I hypersensitivity reactions to foods. IgE responses are known as "immediate" or anaphylactic responses. Direct exposure to the basophils and mast cells in the GI tract lining is usually required to trigger a food allergy reaction, although there are reports of reactions to inhaled foods. Not all reactions are mediated through IgE; though the likelihood of an IgE-mediated clinical reaction often increases with the level of specific IgE.

Wheat allergy may cross react with a variety of other foods and some pollens; additional IgE allergy testing may be indicated. A complete list of foods containing wheat may be found at www.doctorsdata.com under "Hidden Sources of Ingredients".

References:

Siles, Roxanna I. MD and Hsieh, Fred H., MD (2013) Allergy blood testing: A practical guide for clinicians. Cleveland Clinic Journal of Medicine. Dec 2013, 80 (12).